



P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,468	02/07/2000	Ralph Alderson	PF112U1	1320
22195	7590	04/28/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Robert Landsman

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-71 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-71 and 73-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO 800)

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 09, 2004 has been entered.

1. Formal Matters

- A. Claims 42-73 were pending. In the Amendment dated 4/9/04, Applicants canceled claim 72 and added new claims 74-76. Therefore, claims 42-71 and 73-76 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. The rejection of claims 42-71 and 73 under 35 USC 112, first paragraph, regarding the extrapolation of the in vitro model to an in vivo treatment has been withdrawn in view of Applicants' arguments that the in vitro rat retinal explant model is accepted by skilled artisans as correlating with in vivo proliferation and differentiation of retinal cells, including photoreceptor cells. However, new rejections appear below.

B. Claims 42-71 and 73-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method of proliferating photoreceptor cells in vitro, does not reasonably provide enablement for a method of treating a patient by proliferating all types of retinal cells, including photoreceptor cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

First, the breadth of the claims is excessive with regard to Applicants' claiming that VEGF can proliferate any type of retinal cells other than photoreceptor cells. Applicants have only demonstrated that VEGF can proliferate photoreceptor cells and have provided no guidance or working examples that VEGF can proliferate non-photoreceptor retinal cells. Furthermore, it is not predictable to the artisan which retinal cells can be proliferated by VEGF other than photoreceptor cells, nor is it predictable which of these cells will be able to treat an eye disorder.

Furthermore, Applicants have not provided any guidance or working examples as to how to administer these compounds in order to treat the disorder. Applicants have provided a large (10,000-fold) dosing range and various routes of administration. However, no examples exist in the specification for treatment of a subject. In addition, it is not known what effect VEGF would have if it proliferates more than just photoreceptor cells. If the proliferation of cells other than photoreceptor cells is required, it is not understood how Applicants are to specifically target these non-photoreceptor cells.

Therefore, in summary, even though the Example in the specification may use an art-accepted model to proliferate photoreceptor cells, the breadth of the claims is excessive with regard to the use of VEGF to proliferate non-photoreceptor cells. In addition, it is not predictable which cells are able to be proliferated using VEGF, nor have Applicants provided any examples of how to administer VEGF so it can affect the eye. Respectfully, Applicants are claiming every conceivable route of administration and a 10,000-fold dosing range in order to perform a research project to determine how to treat a patient with an eye disorder. For these reasons, the Examiner holds that undue experimentation is required to practice the invention as claimed.

3. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 42-71 and 73-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention. Applicant

have amended claim 42 to recite amino acids 108-188 of SEQ ID NO:2. However, there is no support for this specific fragment in the specification. **This is a new matter rejection.**

4. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 42-71 and 73-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It appears that the method is drawn to treating the cell that has degenerated. It is suggested that claim 42 be amended to recite "to proliferate retinal cells" instead of "to proliferate the retinal cell."

B. Claims 45, 46, 55, 56, 65 and 66 are confusing since it is not clear how one would administer the VEGF compound if it weren't in a pharmaceutical composition

5. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600

